

COMPOSITE STATE BOARD OF MEDICAL EXAMINERS

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COMPOSITE STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENT TO AMEND AND ADOPT RULES

TO ALL INTERESTED PARTIES:

Notice is hereby given by the Composite State Board of Medical Examiners that it intends to amend Chapter 360-32, entitled "Nurse Protocol Agreements Pursuant to O.C.G.A. § 43-34-26.3." An exact copy of the proposed amendments is attached to this Notice.

This notice, together with an exact copy of the proposed rules and a synopsis of the proposed rules are being mailed to all persons who have requested, in writing, that they be placed on a mailing list. A copy of this notice, an exact copy of the proposed rules and a synopsis of the proposed rules may be reviewed during normal business hours of 8:00a.m. to 5:00p.m., Monday through Friday, except official State holidays, at the office of the Composite State Board of Medical Examiners, 2 Peachtree Street, N.W., 36th Floor, Atlanta, Georgia 30303.

Any interested person who will be affected by these rules may present his or her comments to the Board no later than February 27, 2007 or make comments at the public hearing. Comments may be directed to Diane Atkinson, Composite State Board of Medical Examiners, 2 Peachtree Street, N.W., 36th Floor, Atlanta, Georgia 30303-3465 or may be received by the Board by e-mail at matkinson@dch.ga.gov.

A public hearing is scheduled to begin at 8:15 a.m. on March 1, 2007 at the 40th Floor Board Room, 2 Peachtree Street, N.W., Atlanta, Georgia 30303, to provide the public an opportunity to comment upon and provide input into the proposed rules.

The Board voted to adopt this Notice of Intent on February 2, 2007. The attached proposed rules will be considered for adoption by the Board by a teleconference call on March 9, 2007 at 12:00 p.m.

The authority for promulgation of these rules is O.C.G.A. §§ 43-34-24(c), 43-34-26.3, 43-1-19, 43-34-37, 43-1-7, 43-1-25 and the specific statutes cited in the proposed rules.

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The Board will consider at its teleconference meeting on March 9, 2007 at 12:00 p.m. the comments from the March 1, 2007 public hearing whether the formulation and adoption of these proposed rule amendments imposes excessive regulatory costs on any license or entity and whether any cost to comply with the proposed rule amendments could be reduced by a less expensive alternative that accomplishes the objectives of the statutes which are the basis of the proposed rule. Additionally at its teleconference meeting on March 9, 2007, the Board will consider whether it is legal or feasible in meeting the objectives of the applicable laws to adopt or implement differing actions for businesses as listed in O.C.G.A. § 50-13-4(3)(A)(B)(C)(D).

This Notice is adopted and posted in compliance with O.C.G.A. §50-13-4 of the Georgia Administrative Procedures Act.

Date: _____

Signed: _____

LaSharn Hughes, MBA

Executive Director

Composite State Board of Medical Examiners

**ECONOMIC IMPACT AND SYNOPSIS FOR
CHAPTER 360-32
NURSE PROTOCOL AGREEMENTS
PURSUANT TO O.C.G.A. § 43-34-26.3**

ECONOMIC IMPACT:

The attached rules are promulgated under the authority of the Medical Practice Act, Title 43, Chapter 34. The Composite State Board of Medical Examiners licenses and regulates nine professions. The Board will consider at its teleconference meeting on March 9, 2007 the comments from the March 1, 2007 public hearing on whether the formulation and adoption of these proposed rule amendments imposes excessive regulatory costs on any licenses or entity and whether any cost to comply with the proposed rule amendments could be reduced by a less expensive alternative that accomplishes the objective of the statutes which are the basis of the proposed rule. Additionally, at its teleconference meeting on March 9, 2007, the Board will consider whether it is legal or feasible in meeting the objectives of the applicable laws to adopt or implement differing actions for businesses as listed in O.C.G.A. §50-13-43((A)(B)(C)(D).

RULE SYNOPSIS:

AMEND RULE CHAPTER 360-32 NURSE PROTOCOL AGREEMENTS PURSUANT TO O.C.G.A. § 43-34-26.3

Purpose

The purpose of these proposed rules are to provide amendments to Rules Chapter 360-32.

Main Features

Rule 360-32-.01 provides amended definitions applicable to Chapter 360-32. Rule 360-32-.02 provides amended requirements for physicians entering into a nurse protocol agreement with an Advance Practice Registered Nurse (APRN) pursuant to Code Section 43-34-26.3. Rule 360-32-.03 contains amended requirements for the delegating physician's filing of said nurse protocol agreements with the Board. Rule 360-32-.04 provides amended limitations applicable to physicians entering into nurse protocol agreements pursuant to O.C.G.A. § 43-34-26.3. Rule 360-32-.05 provides amended additional requirements regarding physician delegation such as physician responsibility for medical acts performed by the APRN, notification by the delegating physician to the Board of termination of nurse protocol agreement, the availability of the delegating physician for consultation and providing documentation to the Board. Rule 360-32-.06 provides that a delegating or other physician may be disciplined for failure to comply with Chapter 360-32. New Rule 360-32-.07 provides exemptions to the Rules.

**RULES
OF
COMPOSITE STATE BOARD OF MEDICAL EXAMINERS**

CHAPTER 360-32

NURSE PROTOCOL AGREEMENTS PURSUANT TO O.C.G.A. § 43-34-26.3

- 360-32-.01 Definitions
- 360-32-.02 Requirements for Nurse Protocol Agreements Pursuant to Code Section 43-34-26.3
- 360-32-.03 Filing of Nurse Protocol Agreements with the Board.
- 360-32-.04 Limitations.
- 360-32-.05 Additional Requirements Regarding Physician Delegation to an APRN.
- 360-32-.06 Non-compliance
- 360-32-.07 Exemptions

360-32-.01 Definitions. As used in this Chapter the term

(1) "Advanced practice registered nurse", (hereinafter referred to as "APRN"), means a registered professional nurse licensed under Title 43, Chapter 26 of the Official Code of Georgia Annotated, who is recognized by the Georgia Board of Nursing as having met the requirements established by the Georgia Board of Nursing to engage in advanced nursing practice and who holds a masters degree or other graduate degree approved by the Georgia Board of Nursing and national board certification in his or her area of specialty, or a person who is recognized as an advanced practice registered nurse by the Georgia Board of Nursing on or before June 30, 2006.

(2) "~~Alternate Delegating~~ Other Designated Physician" means a physician who:

(a) practices medicine in this state; and

(b) whose scope of practice is the same as that of the "~~Primary~~ Delegating Physician;" and

(c) who has concurred in writing with the terms of the nurse protocol agreement, and has agreed in writing to provide consultation in the absence of the ~~Primary~~ Delegating Physician.

(3) "Board" means the Composite State Board of Medical Examiners.

(4) "Controlled substance" means any controlled substance as defined in Code Section 16-13-21, but shall not include any Schedule I controlled substance included in Code Section 16-13-25 or any Schedule II controlled substance included in Code Section 16-13-26.

- (5) "Dangerous drug" means any dangerous drug as defined in Code Section 16-13-71.
- (6) "Drug" means any dangerous drug or controlled substance.
- (7) "Immediate consultation" means that the delegating physician shall be available for direct communication or by telephone or other telecommunications.
- (8) "Nurse Protocol Agreement" means a written document, mutually agreed upon and signed by an APRN and a physician, by which the physician delegates to that APRN the authority to perform certain medical acts pursuant to Code Section 43-34-26.3, which may include without being limited to, the ordering of drugs, medical devices, medical treatments, diagnostic studies, or in life-threatening situations radiographic imaging tests.
- (9) "Order" means to prescribe pursuant to a protocol agreement, as authorized by Code Section 43-34-26.3, which drug, medical device, medical treatment, diagnostic study, or in life-threatening situations radiographic imaging test is appropriate for a patient and to communicate the same in writing, orally, via facsimile or electronically.
- (10) "Physician" means a person licensed to practice medicine pursuant to Article 2, Chapter 34 of Title 43 and
- (a) Whose principal place of practice is within this state; or
- (b) Whose principal place of practice is outside this state but is within 50 miles from the location where the nurse protocol agreement is being utilized.
- (11) "~~Primary~~ Delegating Physician" means a physician who
- (a) practices medicine in this State; and
- (b) authorizes an APRN to perform certain delegated medical acts pursuant to a nurse protocol agreement.

Authority. O.C.G.A. Secs. 43-34-24, 43-34-26.3

360-32-.02 Requirements for Nurse Protocol Agreements Pursuant to Code Section 43-34-26.3.

- (1) A physician entering into a nurse protocol agreement with an APRN pursuant to Code Section 43-34-26.3 shall include the following general data in the protocol agreement:
- (a) Names, addresses, telephone numbers, license numbers, and DEA registration number for all parties to the nurse protocol agreement, including any other designated alternate delegating physicians that will be utilized if the delegating physician is not available;

(b) The delegating physician must provide the APRN's DEA number to the Board within 30 days of issuance.

~~(b)~~ (c) Description of practice and number of locations, including primary and proposed satellite site(s);

~~(e)~~ (d) Dates of initiation and amendments. Any amendments made to the protocol agreement shall be filed with the Board for review within 30 days of execution; and

~~(d)~~ (e) Information regarding the specialty area or field of the APRN.

(2) The agreement shall contain a provision for immediate consultation, as defined in rule 360-32-.01, between the APRN and the delegating physician.

(3) If the delegating physician is not available for consultation, the delegating physician may designate ~~another alternate delegating physician~~ who concurs with the terms of the nurse protocol agreement. The designation of another physician ~~an alternate delegating physician~~ must also meet the following terms:

(a) Such designation by the delegating physician shall be in writing and attached to the nurse protocol agreement;

(b) Such designation must be to a physician whose scope of practice is the same as that of the ~~primary~~ delegating physician; and

(c) Such designation must include the printed name, license number and signature of the ~~alternate other designated delegating physician~~ with an affirmation from the other designated alternate delegating physician that he or she has agreed to serve as an alternate, other designated physician, has reviewed the nurse protocol agreement and concurs with the terms of the agreement.

(4) The nurse protocol agreement shall outline and identify the applicable standard of care and shall be specific to the patient population seen.

(5) The nurse protocol agreement shall identify the parameters under which the delegated act may be performed by the APRN, including but not limited to;

(a) ~~A formulary of drugs,~~ Drugs, devices, medical treatments, diagnostic studies that may be ordered and implemented by the APRN.

(b) Circumstances under which a prescription drug order or device may be executed;

~~(c) Requirement that dosage units shall be limited up to a ninety (90) day supply;~~

~~(d) Number of refills which may be ordered; however, in no event may the protocol authorize refills for more than twelve (12) months from the date of the original order except in the case of oral contraceptives, hormone replacement therapy, or prenatal vitamins which may be refilled for a period of twenty-four (24) months;~~

(c) Number of refills which may be ordered. Nothing in this Rule shall be construed to authorize an advanced practice registered nurse to issue a prescription drug order for a Schedule I or II controlled substance or authorize refills of any drug for more than 12 months from the date of the original order except in the case of oral contraceptives, hormone replacement therapy, or prenatal vitamins which may be refilled for a period of 24 months as provided in O.C.G.A. 43-34-26.3.

(d) Provide that a patient who receives a prescription drug order for any controlled substance pursuant to a nurse protocol agreement shall be evaluated or examined by the delegating physician or other physician designated by the delegating physician as provided in O.C.G.A. 43-34-26.3 on at least a quarterly basis or at a more frequent interval as consistent with the minimum acceptable standards of the practice of medicine as determined by the Board.

~~(e) Provide that the delegating physician shall personally reevaluate a patient, at least every (3) months if the patient receives controlled substances and provide that the delegating physician shall personally reevaluate all other patients at a frequency consistent with the minimum acceptable standards of the practice of medicine in the State of Georgia;~~

~~(f) (e) Extent to which radiographic image tests may be ordered in life-threatening situations;~~

~~(g) (f) A predetermined plan for emergency services;~~

~~(h) (g) If the delegating physician authorizes the APRN to order an X-ray, ultrasound or radiographic imaging test, the nurse protocol agreement shall contain provisions whereby such tests shall be read and interpreted by a physician who is trained in reading and interpretation of such tests and provide that a copy of such report shall be forwarded to the delegating physician. However, such provision for an ultrasound shall not be required for an APRN acting within his or her scope of practice as authorized by Code Sections 43-26-3 and 43-26-5;~~

~~(i) (h) A section that details specific patient conditions and circumstances that require direct, on-site evaluation or consultation by the delegating physician; and~~

~~(j) (i) If the protocol agreement delegates authority to the APRN to prescribe/order prescription drugs, then a section that specifically provides that such delegation does not include the authority to prescribe/order prescription drugs intended to cause an abortion to occur pharmacologically.~~

(6) The nurse protocol agreement shall require documentation by the APRN of those acts performed by the APRN that are specific to the medical acts authorized by the delegating physician and provide that, if the APRN has prescribing authority pursuant to the protocol agreement, each prescription shall be noted in ~~on~~ the patient's chart ~~and the physician shall countersign a copy of the prescription drug order for controlled substances or medical record.~~ entry within a reasonable time, not to exceed thirty (30) days, ~~unless the countersignature is required sooner by a specific law, regulation or by a specific nurse protocol agreement~~

(a) If the protocol agreement delegates authority to the APRN to prescribe/order prescription drugs or devices, a copy of the prescription drug or device order delivered to the patient shall be maintained in the patient's medical file. For purposes of this paragraph a copy shall mean a duplicate prescription or a photocopy or electronic equivalent.

(b) If the protocol agreement delegates authority to the APRN to prescribe/order prescription drugs or devices, the protocol shall provide that the prescription/order shall be issued on a form which contains the following:

1. The name, address and telephone number of the delegating physician, the name of the APRN, the APRN's DEA number, if applicable, and the name and address of the patient, the drug or device prescribed, the number of refills and directions to the patient with regard to taking and dosage of the drug; and

2. The form/prescription shall be signed by the APRN and shall be on a form which shall include, without limitation, the names of the APRN and delegating physician who are parties to the nurse protocol agreement. shall utilize the following language:

"This prescription authorized through (delegating physician name), (M.D. or D.O.) by (APRN's name), APRN."

(7) ~~The nurse protocol agreement shall include a schedule for periodic review of patient records. The Board has determined that the minimum accepted standards of medical practice require the following:~~

~~(a) that the delegating physician review and sign 100% of patient records for patients receiving prescriptions for controlled substances and 100% of patient records in which an adverse outcome has occurred, and 25% 100% of patient records for patients receiving prescriptions for chronic illnesses, and 25% of all other patient records; and~~

~~(b) that such review occur no more than 30 days after issuance of the controlled substance prescription and no more than 30 days after the discovery of an adverse outcome, and no less than once every 12 months for patients receiving prescriptions for chronic illnesses, and that such review of 25% of all other patient records occur no less than once every 30 days.~~

(7) The nurse protocol agreement shall include a schedule for periodic review of patient records. The Board has determined that the minimum accepted standards of medical practice require the following:

(a) In as much as O.C.G.A. 43-34-26.3 requires that a delegating physician or other designated physician evaluate or examine all patients who receive any controlled substance prescription pursuant to a nurse protocol agreement, a delegating physician or other designated physician must review and sign 100% of patient records for patients receiving prescriptions for controlled substances to comply with the law. Such review shall occur at least quarterly after issuance of the controlled substance prescription.

(b) The delegating physician review and sign 100% of patient records in which an adverse outcome has occurred. Such review shall occur no more than 30 days after the discovery of an adverse outcome.

(c) The delegating physician review and sign 25% of all other patient records. Such review shall occur at least annually.

(8) The nurse protocol agreement shall indicate whether the APRN is authorized under the nurse protocol agreement to request, receive and sign for professional samples and whether the APRN may distribute professional samples to patients. If the protocol authorizes the APRN to request, receive, sign for and/or distribute professional samples to patients, the protocol agreement must:

(a) include a list of the professional samples approved by the physician for request, receipt and distribution by the APRN;

(b) contain a provision requiring the recording of a complete list of the specific number and dosage of each professional sample and medication voucher received and dispensed; and

(c) provide that all professional samples shall be maintained as required by applicable state and federal laws and regulations.

(8) The nurse protocol agreement shall indicate whether the APRN is authorized under the nurse protocol agreement to request, receive and sign for professional samples.

(a) If the nurse protocol agreement provides this authority, the APRN shall comply with O.C.G.A. 43-34-26.3 which states: An advanced practice registered nurse may be authorized under a nurse protocol agreement to request, receive, and sign for professional samples and may distribute professional samples to patients. The office or facility at which the advanced practice registered nurse is working shall maintain a list of the professional samples approved by the delegating physician for request, receipt, and distribution by the advanced practice registered nurse as well as a complete list of the specific number and dosage of each professional sample and medication voucher received and dispensed. In addition to the requirements of this Code section, all

professional samples shall be maintained as required by applicable state and federal laws and regulations.

(9) Copies of the nurse protocol agreement shall be ~~maintained~~ available at each practice site where the APRN is authorized to perform the delegated acts and shall be made available upon written request by the Board to the physician at the appropriate practice site.

(10) The nurse protocol agreement shall be dated and signed by the delegating physician, ~~alternate~~ other designated ~~delegating~~ physician, if applicable, and the APRN.

(11) The nurse protocol agreement shall be reviewed and updated at least annually. Said reviewed and updated protocol agreement shall be filed with the Board within 30 days after such review and update has occurred.

Authority. O.C.G.A. Secs. 43-34-24, 43-34-26.3

360-32-.03 Filing of Nurse Protocol Agreements with the Board.

(1) The delegating physician shall file the nurse protocol agreement and a Board approved ~~application~~ form with the Board for review and submits the requisite fee for review established in the Board's fee schedule.

(2) In addition to submitting the nurse protocol agreement to the Board for review, the delegating physician shall obtain from the APRN and submit to the Board current verification from the Georgia Board of Nursing that the APRN is approved to practice as an APRN and whether the APRN has had any disciplinary action taken against him or her by the Georgia Board of Nursing.

(3) If, after review, the Board determines that the nurse protocol agreement fails to meet accepted standards of medical practice, the delegating physician will be so notified and be required to amend the agreement in order to comply with such accepted standards.

(4) The delegating physician shall file with the Board amendments to nurse protocol agreements previously reviewed by the Board within 30 days of the date the amendment was executed.

(5) Nurse protocol agreements must be received by the Board ~~executed within ninety (90) days from the effective date of this rule shall be filed with the Board within ninety (90) days from the date of execution. Nurse protocol agreements executed after ninety (90) days from the effective date of this rule shall be filed with the Board for review within 30 days from the date of execution of the agreement.~~

Authority. O.C.G.A. Secs. 43-1-7, 43-34-24, 43-34-26.3.

360-32-.04 Limitations.

- (1) A physician whose medical license is restricted shall not enter into a nurse protocol agreement, unless the physician has received prior written approval from the Board.
- (2) No physician shall delegate authority to an individual pursuant to the provisions of Code Section 43-34-26.3, unless the individual is fully approved by the Georgia Board of Nursing to practice as an APRN.
- (3) No physician may enter into a nurse protocol agreement with an APRN whose specialty area or field is not comparable to the physician's specialty area or field.
- ~~(4) No physician shall enter into a nurse protocol agreement with an APRN who has been disciplined by the Georgia Board of Nursing, unless the physician has received prior written approval from the Board to act as a delegating physician of that APRN.~~
- ~~(5)~~ (4) Unless specifically exempted by paragraph (g) of Code Section 43-34-26.3, a delegating physician may not enter into a nurse protocol agreement with more than four APRN's at any one time.
- ~~(6)~~ (5) Except for practice settings identified in paragraph (7) of subsection (g) of Code Section 43-34-26.3, a physician shall not be an employee of an APRN, alone or in combination with others, if the physician delegates authority to and/or is required to supervise the employing APRN.

Authority. O.C.G.A. Secs. 43-34-24(c), 43-34-26.3.

360-32-.05 Additional Requirements Regarding Physician Delegation to an APRN.

- ~~(1) The delegating physician shall file the nurse protocol agreement and a Board approved application form with the Board for review and submits the requisite fee for review established in the Board's fee schedule.~~
- ~~(2) In addition to submitting the nurse protocol agreement to the Board for review, the delegating physician shall obtain from the APRN and submit to the Board current verification from the Georgia Board of Nursing that the APRN is approved to practice as an APRN and whether the APRN has had any disciplinary action taken against him or her by the Georgia Board of Nursing.~~
- (1) The delegating physician shall be available for immediate consultation with the advanced practice registered nurse. If the delegating physician is not available, the delegating physician for purposes of consultation may designate another physician who concurs with the terms of the nurse protocol agreement as provided in O.C.G.A. 43-34-26.3.

(2) The delegating physician shall document and maintain a record of onsite observation and review of medical records on a quarterly basis to monitor quality of care being provided to the patients.

(3) The delegating physician shall make certain that the medical acts provided by the APRN pursuant to the protocol agreement are:

(a) Commensurate with the education, training, experience and competence of the APRN:

1. A delegating physician shall therefore ensure that an APRN to whom he delegates prescriptive authority receives pharmacology training appropriate to the delegating physician's scope of practice at least annually. Documentation of such training shall be maintained by the physician and provided to the Board upon request.

2. A delegating physician who fails to comply with subparagraph (3)(a)1 of this rule by delegating prescriptive authority to an APRN who has not received pharmacology training appropriate to the delegating physician's scope of practice at least annually may be subject to disciplinary action.

(b) Within the scope of practice, specialty area or field and certification of the APRN;

(c) Within the comparable specialty area or field of the delegating physician; and

(d) Well documented in accurately maintained patient specific medical records.

(4) The delegating physician is responsible for all the medical acts performed by the APRN.

(5) A delegating physician shall notify the Board within ten (10) working days of the date of termination of a nurse protocol agreement with the delegating physician and APRN.

(6) The Board may request at any time to review the nurse protocol agreement and any supporting documentation. Failure to provide this written information to the Board within 30 days shall be a basis for and may result in disciplinary action. The Board may require changes in these documents if the Board determines that they do not comply with O.C.G.A. 43-34-26.3 and/or accepted standards of medical practice.

(7) The Board may request at any time documentation of the delegating physician's review of the medical acts performed by the APRN pursuant to a nurse protocol agreement. Failure to provide written documentation to the Board within 30 days shall be a basis for and may result in disciplinary action.

Authority. O.C.G.A. Secs. 43-34-24, 43-34-26.3, 43-34-37, 43-1-19, 43-1-25.

360-32-.06 Non-compliance.

2/7/2007

A delegating or ~~alternate delegating~~ other designated physician may be disciplined for failure to comply with this Chapter.

360-32-.07 Exemptions

Nothing in this rule shall be construed to require a physician to delegate prescriptive authority or prohibit a physician from utilizing the protocol authority granted under O.C.G.A. §43-34-26.1.

Authority OCGA Secs. 43-34-24, 43-34-26.3